

other skin related conditions that need require benzoyl peroxide and clindamycin combination. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

...In this case, Baroody provides the teaching that the composition containing the above active agents are limited by storage stability and also suggests several factors such as pH, viscosity, gelling agent contribute to the stability (col. 3 L 14-36, table 3). In the same section, Baroody describes mixing a suspension of benzoyl peroxide with a solution of clindamycin (which meets the process steps a-c of instant claims) and also state that the viscosity may be relatively low and high, suggesting that it may be varied. Thus, Baroody is directed to solving the same problem (nature of problem) as that of instant.

...In response, a person of ordinary skill in the art reading Baroody would readily recognize that maintaining stability of the composition is important and in order to do so, factors such as pH, viscosity, amounts of gelling agent etc., should be varied. While Baroody does not teach the final viscosity is lower than initial viscosity, Baroody teaches mixing the same components (a benzoyl peroxide suspension reads on instant dispersion of step a of claim 26) with a clindamycin solution (step b of claim 26). In addition, instant claims generally state that the viscosity is lower without actually stating by how much the viscosity is lower. The claims also fail to recite the period of stability so as to distinguish from that of Baroody. In light of the teachings of Baroody, the actual application of the technique to stabilize the composition is not beyond the skill of an ordinary person, which according to the above KSR ruling would have been obvious. The reasonable expectation in this case that varying the pH and gelling agents and viscosity results in various stability of the composition.

Applicants respectfully traverse this rejection.

The Examiner has failed to establish a *prima facie* case of obviousness against the presently rejected claims. To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. _____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may]

be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (KSR, *supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

The presently pending claims relate to a process for preparing a storage-stable topical composition that requires mixing a benzoyl peroxide intermediate dispersion having a viscosity of 60,000 to 250,000 centipoises and a clindamycin intermediate solution, such that the final composition has a viscosity of 50,000 to 200,000 which is *lower than the viscosity of the benzoyl peroxide dispersion before mixing*. This final viscosity that is lower than the viscosity of the benzoyl peroxide dispersion demonstrates that the resulting composition prepared by the presently claimed process are easier to mix together, contain less degradates and have a greater degree of

uniformity than those compositions previously known in the art, including those from the Baroody reference (see, at page 15, lines 4-9 of the instant application).

In contrast, at col. 4, lines 44-52, Baroody specifically disclose a process for preparing the topical composition by combining or admixing an aqueous gel suspension of benzoyl peroxide with an aqueous solution of a clindamycin salt or ester, where the benzoyl peroxide suspension is initially combined with a gelling agent to form a first component of a two-component kit. The gelling agent is selected to have a *reduced viscosity* at the pH of the first component and *an increased viscosity* at the stage of the final product obtained by the combination. Similarly, at col. 6, lines 3-6, Baroody specifically disclose that "when the benzoyl peroxide component is combined with the clindamycin component, the resulting combined product will have an increased pH resulting in *enhanced viscosity* within the range set forth above." (Emphasis added) Further, at col.6, lines 22-23, Baroody discloses that "*a beneficial increase* in viscosity can be achieved". (Emphasis added)

The Baroody reference does not teach, disclose, or render obvious any of the presently pending claims because it fails to disclose the requirement of the presently pending claims that the claimed process results in a final composition having a viscosity lower than the viscosity of the intermediate benzoyl peroxide dispersion. Instead, Baroody actively teaches the exact opposite, requiring the final composition to have a viscosity *higher* than the benzoyl peroxide intermediate composition. This would motivate one skilled in the art who wishes to invent a storage-stable clindamycin topical composition, to avoid taking the opposite relative viscosity between the benzoyl peroxide and the final composition as in the presently pending claims.

Further, the Baroody reference contains no suggestion or incentive to motivate the Baroody reference teachings to reach the presently claimed process. Accordingly, there is no reason for one skilled in the art to take the presently claimed process to prepare the composition of clindamycin and benzoyl peroxide, where the viscosity of the final composition is relatively lower than that of the benzoyl peroxide, which is the exact opposite of the teachings in the Baroody reference.

In addition, applicants submit that the teachings of the Baroody reference are not such general conditions for the presently pending claims as recited in *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), but instead are the opposite conditions teaching away from the presently pending claims. Accordingly, it is not appropriate for the Examiner to recite *In re Aller* to negate the nonobviousness of the presently pending claims 26-31.

As such, the Baroody reference does not teach, disclose, or render obvious the presently pending claims 26-31. Accordingly, applicants respectfully request the Examiner to reconsider and withdraw the rejection of presently pending claims 26-31.

CONCLUSION

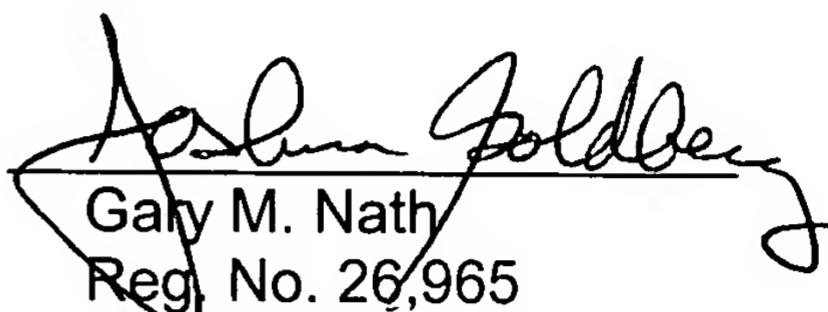
Based upon the above remarks, the presently claimed subject matter is believed to be novel and patentably distinguishable over the prior art of record. The Examiner is therefore respectfully requested to reconsider and withdraw the outstanding rejection and allow all pending claims 26-31. Favorable action with an early allowance of the claims pending in this application is earnestly solicited.

The Examiner is welcomed to telephone the undersigned attorney if she has any questions or comments.

Respectfully submitted,
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